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09/673,292

10/13/2000

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12/19/2003

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,292

Applicant(s)

FAUSTMAN, DENISE L.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Election/Restriction

Applicant's response to the restriction requirement received on 9/2/03 has been entered. Applicant's election of the subject matter of Group I is acknowledged. However, the applicant correctly pointed out in their response that the instant application has 42 claims whereas the parent application only had 32. Since the previous restriction requirement listed the incorrect claims and claim subject matter, the previous restriction requirement has been **withdrawn** and a new restriction requirement is presented below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 3, 5-6, 9, 11-12, 15, 17-18, 21,23-24, 27, and 29-30, drawn to nucleic acids encoding a TAP2 splice variant, vectors encoding said nucleic acids, host cells transformed with said vectors, methods of producing polypeptides using said host cells, and methods of altering peptide transport in a cell using said nucleic acids, classified in classes 536, 435, and 514, subclasses 23.1, 320.1 and 325, and 44.
- II. Claims 4, 10, 16, 22, and 28, drawn to nucleic acids encoding a TAP1 splice variant, vectors encoding said nucleic acids, host cells transformed with said vectors, methods of producing polypeptides using said host cells, and methods of

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altering peptide transport in a cell using said nucleic acids, classified in classes 536, 435, and 514, subclasses 23.1, 320.1 and 325, and 44.

- III. Claims 31, 35, and 36, drawn to TAP1 splice variant polypeptides , classified in class 530, subclasses 300 and 350.
- IV. Claims 32-34, drawn to TAP2 splice variant polypeptides , classified in class 530, subclasses 300 and 350.
- V. Claims 37-39, drawn to antibodies, classified in class 530, subclass 387.1.
- VI. Claim 40, drawn to methods for treating a disorder comprising gene therapy to provide normal TAP heterodimer expression, classified in class 514, subclass 44.
- VII. Claim 41, drawn to methods for broadening the immune response by introducing lymphocytes transfected ex vivo to express a TAP isoform, classified in class 424, subclass 93.1.
- VIII. Claim 42, drawn to a method for diagnosing or monitoring a disease comprising determining the expression of a TAP isoform in a sample, classified in class 435, subclass 4.

Please note that claims 1-2, 7-8, 13-14, 19-20, and 25-26 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-2, 7-8, 13-14, 19-20, and 25-26. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending

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from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

1) Inventions I and II, and inventions III and IV are separately patentable inventions each from the other. TAP1 and TAP2 are separate and distinct genes which comprise distinct nucleic acid sequences encoding distinct polypeptides. The TAP1 and TAP2 gene products are not equivalent in function or structure and have distinct physical, chemical, and functional properties. As such, it is proper to separate two distinct genes encoding distinct proteins each from the other.

2) Inventions I and III, and Inventions II and IV are related to each other in part as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptides of inventions III and IV can be made

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by using an amino acid synthesizer, or by isolating said naturally occurring polypeptides from human cells, and do not require the nucleic acids of inventions I and II. Furthermore, nucleic acids and polypeptides are not related in that nucleic acids have substantially different physical, structural, chemical, and functional properties than polypeptides, are made using different reagents and methods, and are used for substantially different purposes, such as the use of the nucleic acids in hybridization assays.

3) Inventions I-IV are further patentably distinct from invention V in that the nucleic acids, vectors and host cells of inventions I-II, the polypeptides of invention III and IV, and the antibodies of invention V have substantially different structures and properties, are made using substantially different techniques, have different modes of operation, different functions, and different effects, and can be used for substantially different purposes.

4) Inventions I and II are patentably distinct from invention VI in that the methods of invention VI is an *in vivo* method of treating a disease using gene therapy, whereas the methods of invention I are directed to *in vitro* methods comprising cells in culture. Further, the methods of invention VI can be practiced without the nucleic acids of inventions I and II. The method of gene therapy in invention VI is very broad. It reads on diseases associated with overexpression or underexpression of a TAP isoform. The cause of the overexpression or underexpression of the TAP isoforms is not clear. Thus, nucleic acids other than those recited in inventions I and II may be required to achieve normal TAP heterodimer expression.

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5) Inventions I and II are patentably distinct from invention VII. The cells of inventions I and II may be used for substantially different purposes than introduction into a mammal for broadening an immune response, such as the use of the cells to produce protein in cell culture, or the use of the cells in vitro assays. Further, the methods of inventions I and II are cell culture methods that do not include the additional steps in invention VII directed to re-introducing the cells into an individual, and also determining TAP isoform expression in the individual.

7) Inventions III-V are patentably distinct from inventions VI and VII in that the methods of invention VI and VII involve the use of nucleic acids and do not require or depend on the polypeptides and antibodies of inventions III-V.

8) Inventions I-VII are patentably distinct from invention VIII in that the diagnostic method of invention 8 does not require the nucleic acids, proteins, or antibodies of inventions I-V for its practice, since the method involves the detection of protein or mRNA. Further, while the method of invention VII includes a detection step, the method of invention VII further requires transfecting cells with a TAP isomer and administering the cells to an individual not required for invention VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different search requirements, and different classification, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306.

Please note that the United States Patent and Trademark Office will begin to move to the new campus in Alexandria, Virginia, in December 2003. The examiners of Art Unit 1632 will be moving in January 2004. As of January 13, 2004, this examiner's phone

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number will be (571) 272-0737, and that of the examiner's supervisor will be (571) 272-0734.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read 'Anne M. Wehbé', with a long horizontal stroke extending to the right.